King, Valerie A.

From: Michael Szwanek (402)437-4880 [Michael.Szwanek@mdsps.com]
Sent: Thursday, September 11, 2003 1:33 PM
To: maria.gogova@pmusa.com; barbara.k.zedler@pmusa.com; valerie.a.king@pmusa.com
Cc: Paul Johnson; Kimberly Prchal
Subject: Amendments for Marlboro Studies

Sensitivity: Confidential

AA05796_AMEND HREE_10SEP03_Ph.

AA05624_AMEND WO_10SEP03_Phil..

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All,

Attached are the proposed Amendments to the short and long term Marlboro studies increasing the number of subjects as requested (i.e., enroll up to 350 to randomize a total of 225 or 75 for each group) for your review. Redline ICF for Phoenix and Lincoln sites also attached. Spanish translation will occur following IRB approval.

These documents will be going to the Sept 23 IRB and need to submitted to the IRB secretary by Sept 17 (Wed). Please let me know if there are any changes/corrections prior to this date. Otherwise I will submit the documents as is.

Thanks,

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